REMARKS

Claims 1-15, 17, 23, 24, and 28 have been cancelled and claims 22 and 25 have been amended herein. No new matter is added by virtue of the amendments, as support for the amendments lies in the original claims as filed. Entry and consideration of the amendments contained herein is requested.

Claims 22, 24, and 26-45 were rejected under 35 USC § 102(e) as anticipated by Mo et al. (US 2004/0131664, effective filing date January 3, 2003).

Applicant has amended independent claim 22 herein. Amended claim 22 recites:

A method of treating premature ejaculation in a patient needing such treatment comprising the steps of:

administering meatally to a patient in need of treatment of premature ejaculation an ejaculation latency prolonging amount of a semi-solid composition comprising:

from about 0.01 to about 4 percent by weight based on the weight of the composition of a topical anesthetic;

from 0.1 percent to 0.5 percent by weight based on the total weight of the composition of a vasoactive prostaglandin selected from the group consisting of prostaglandin E_1, a pharmaceutically acceptable salt thereof, a lower alkyl ester thereof wherein the lower alkyl is a straight chain or branched chain alkyl containing one to four carbon atoms, and a mixture thereof;

a polymeric thickener selected from the group consisting of a shear-thinning polysaccharide gum and shear-thinning polyacrylic acid polymer;

a lipophilic component that is selected from the group consisting of an aliphatic C_1 to C_8 alcohol, an aliphatic C_8 to C_{30} ester, a liquid polyol and a mixture thereof;

water; and

a buffer system that provides a buffered pH value for said composition in the range of about 3 to about 7.4;

wherein administering the semi-solid composition administers about 0.1 mg to about 0.5 mg of vasoactive prostaglandin and confers prolongation of ejaculation latency to the patient, thereby treating premature ejaculation in the patient.

Amended claim 22 incorporates the limitations of prior claims 23, 24, and 28 (now cancelled). The Office Action has acknowledged prior claim 23 as not anticipated by Mo et al. Thus, it is believed the present amendments render the rejection under 35 USC §102 moot. For the same reasons, it is believed dependent claims 25-27 and 29-45 are also not anticipated by Mo et al. Withdrawal of the rejection is thus respectfully requested.

Claims 23 and 25 were rejected under 35 USC §103(a) as unpatentable over Mo et al., in view of Sallis (US 2003/0144318) and further in view of Samour et al. (US 5,942,545).

I. Mo was owned or subject to an obligation of assignment to the same owner as the subject application at the time the instant invention was made.

Mo et al. (US 2004/0131664, published July 8, 2004, effective filing date January 3, 2003) is prior art to the instant application only under 35 USC §102(e). Mo et al. and the instant application were owned by or subject to an obligation of assignment to the same owner, at the time the invention was made. See Declaration of Vivian H. Liu Under 37 CFR §1.132 (hereinafter Liu Declaration) submitted herewith, at paragraphs 5 and 7-9.

Under 35 USC §103(c)(1):

> *Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.*

Thus, because Mo et al. is prior art only under 35 USC §102(e), and the application was owned by the same owner and/or subject to an obligation of assignment to the same owner at the time the instant invention was made, the Mo et al. reference shall not preclude patentability under an obviousness rejection under 35 USC §103(a), and should be disqualified as art under 35 USC §103(a).

II. Sallis and/or Samour et al. do not render the instant invention obvious.

Sallis

The disclosure of Sallis teaches methods of treatment of male sexual dysfunction by intracavernosal pharmacotherapy (ICP) using at least one vasodilator. Sallis recognizes prior use of PGE_1, as well as previous drawbacks of administration of PGE_1 by urethral administration for treatment of erectile dysfunction, including the negative side effects conferred by such administration. See Sallis at paragraph [0013]. Sallis teaches ICP administration of a three-drug mixture comprising papaverine, phentolamine *and* PGE_1 is preferred for induction of response, as well as decreasing incidence of negative side effects. See Sallis at paragraph [0014]. Furthermore, Sallis teaches only that administration of vasodilator compositions (including, e.g., PGE_1) should be administered intracavernosally (i.e., by ICP) "because this method delivers the medication to its precise site of action (i.e., the corpus cavernosum), minimizing unwanted side effects..." See Sallis at paragraph [0051].

Sallis describes methods of treatment of sexual dysfunction as including: "sexual dysfunction treatable by the method can be erectile dysfunction. Premature ejaculation can also be treated." See Sallis at paragraph [0018]. However, Applicant points out that Sallis also recognizes that dosage and treatment of erectile dysfunction (ED) and treatment of premature ejaculation (PE) are separable and not interchangeable, contrary to the conclusion that "one of ordinary skill in the art would have been motivated to administer such an amount of prostaglandin E to treat premature ejaculation as it is another sexual dysfunction in the expectation of attaining similar therapeutic benefits and safety" as asserted in the present Office Action. See Office Action at page 5, first paragraph. For example, at paragraph [0066], Sallis describes an exemplary dosage table having columns to separate patients with ED and PE because "patients with PE tend to require a more conservative adjustment than those with ED." See Sallis at paragraph [0066].

Furthermore, Applicants point out the disorders of ED and PE are distinct and do not have the same clinical characteristics or efficacy variables. See The Merck Manual of Diagnosis and Therapy. (Beers, M.H. and Berkow, R., eds., Merck Research Laboratories, Whitehouse Station, N.J. 17th ed. 1999), at pages 1558-1559 and pages 1836-1838. Erectile dysfunction is characterized by the inability to attain or sustain an erection of the penis. The primary efficacy variable for ED is the ability to attain and sustain an erection in order to achieve penetration. See, e.g., The Merck Manual at pages 1836-1838, Sallis at paragraphs [0046] to [00052] and Fig 1 and Fig 2. In contrast, premature ejaculation is characterized by orgasm and ejaculation with minimal stimulation and may occur before, during or shortly after penetration. The primary efficacy variable for PE is the ability to achieve a prolonged ejaculatory latency time (ELT), for example, longer than two minutes. See, e.g., The Merck Manual at pages 1558-1559 and the instant specification at page 35.

Thus, in view of the facts that the disorders of ED and PE are separable and do not have either the same or overlapping clinical characteristics or efficacy variables, one would not expect a composition and dose useful for the treatment of ED would also provide an efficacious composition and dose for the treatment of PE. Furthermore, where administration of PGE_1 has previously demonstrated variable efficacy and association with negative side effects, depending on composition, dose and/or route of administration, one would not expect administration to treat a PE would be effective even if such a composition were shown to be an effective for treatment of ED.

Samour et al.

The disclosure of Samour et al. teaches the use of dioxanes and dioxolanes as unique delivery agents for compositions for administration of PGE_1. The complete teaching of Samour et al. recognizes prior use of prostaglandin PGE_1 for the treatment of erectile dysfunction. However, the reference acknowledges prior administration via transdermal administration was ineffective, and/or administration

via intracavernosal administration resulted in unbearable side effects, including penile pain. See Samour et al. at column 3, line 57 through column 4, line 38. Samour et al. also teaches dioxanes and dioxolanes are unique penetration enhancers and replacement with another penetration enhancer would not be useful in preparation of prostaglandin compositions for treatment of erectile dysfuntion. In particular, the reference states:

> *...delivery of elevated drug levels via a non-vascular route directly into target sites deep below the skin was not to be expected. The well vascularized dermis would be expected to rapidly remove a drug before it can penetrate into the deeper target tissues, in this case, the corpora cavernosa and spongiosum. Furthermore, the cavernosa are covered by a thick tissue, the tunica albuginea, whose barrier properties are very different from that of the skin.*

See Samour et al. at column 5, lines 10-18. Samour et al. thus teaches that replacement of a prostaglandin containing composition provided by Samour et al. with another composition containing a different penetration enhancer would not be expected to be useful for therapy. Because of the adverse side effects and/or inefficacy of prior art compositions, and the reference teaching that dioxanes and dioxolanes have particular properties which distinguish provided compositions from other prostaglandin compositions comprising penetration enhancers, Samour et al. is a teaching away from the use of prostaglandin compositions generally for the treatment of erectile dysfunction and relief of erectile impotence. In view of this teaching, one would not expect use of the compositions to provide efficacious effects for treatment of erectile dysfunction, or premature ejaculation.

The teachings of Sallis and Samour et al. do not provide one skilled in the art with knowledge or direction such that the instant claims would be obvious. Male sexual dysfunction disorders of ED and PE are separable conditions with different clinical presentations and efficacy variables. Furthermore, the use of prostaglandin compositions (including, e.g., compositions comprising PGE_1) for the treatment of erectile dysfunction was known to provide variable efficacy for erectile dysfunction, depending on the dose, composition, and/or route of administration. Additionally, administration of prostaglandin, including, e.g., PGE_1, was known to confer negative, unbearable side effects under certain conditions. In view of these factors taken together, one would not expect administration of a composition comprising PGE_1 would confer efficacious results for the treatment of PE. In particular, nothing in the teachings of Sallis and/or Samour et al., whether alone or in combination, provides direction to one skilled in the art such that one would generate PGE_1 containing compositions for use in the treatment of PE according to the present claims. In fact, the teachings in Sallis and Samour et al., in conjunction with the knowledge in the art at the time, provide no expectation that the instant methods would successfully confer efficacy for

treatment of PE. Thus, the instant claims cannot be obvious in view of the reference teaching. Reconsideration and withdrawal of the rejection under 35 USC §103(a) is therefore requested.

Claims 22-43, 47, and 48 were rejected under 35 USC §103(a) as unpatentable over Okada et al. (US 2003/0220292) in view of Sallis (US 2003/0144318) and further in view of Samour et al. (US 5,942,545).

I. Okada et al. was owned or subject to an obligation of assignment to the same owner as the subject application at the time the instant invention was made.

The instant application claims the benefit of U.S. Provisional Application No. 60/456,604, filed March 21, 2003 and to U.S. Provisional Application No. 60/456,813, filed March 21, 2003. The content of the specification and the instant claims are fully supported in the provisional applications. Therefore, the instant claims should be accorded the benefit of the filing date of March 21, 2003.

Okada et al. was published November 27, 2003, and the instant application should be accorded the benefit of a filing date of March 21, 2003. Thus, Okada et al. is only available as prior art to the instant application under 35 USC §102(e). Okada et al. (US 2003/0220292) and the instant application were owned by or subject to an obligation of assignment to the same owner, at the time the invention was made. See Liu Declaration at paragraphs 6-8 and 10. For the same reasons discussed above for Mo, the Okada et al. reference shall not preclude patentability under an obviousness rejection under 35 USC §103(a), and should be disqualified as art under 35 USC §103(a).

II. Sallis and/or Samour et al. do not render the instant invention obvious.

For the reasons discussed above, the teachings of Sallis and/or Samour et al., whether alone or in combination, do not render the instant claims obvious. Reconsideration and withdrawal of the rejection under 35 USC § 103(a) is respectfully requested.

If at any time a telephone discussion would assist the Examiner and/or advance prosecution, please contact the undersigned.

This paper is being filed timely as it is being filed with a request for a three month extension of time. It is believed no additional fees and/or extensions of time are required. In the event any additional extensions of time, fees and/or credits are necessary, please consider this a conditional petition therefor. The undersigned hereby authorizes the requisite fees to be charged and/or credited accordingly to Deposit Account No. 50-1582.

Respectfully submitted,

December 21, 2007 MIRICK, O'CONNELL, DEMALLIE & LOUGEE, LLP

By _____

Kerri Pollard Schray
Registration No. 47,066
1700 West Park Drive
Westborough, MA 01581
Telephone – 508-898-1501
Facsimile – 508-898-1502